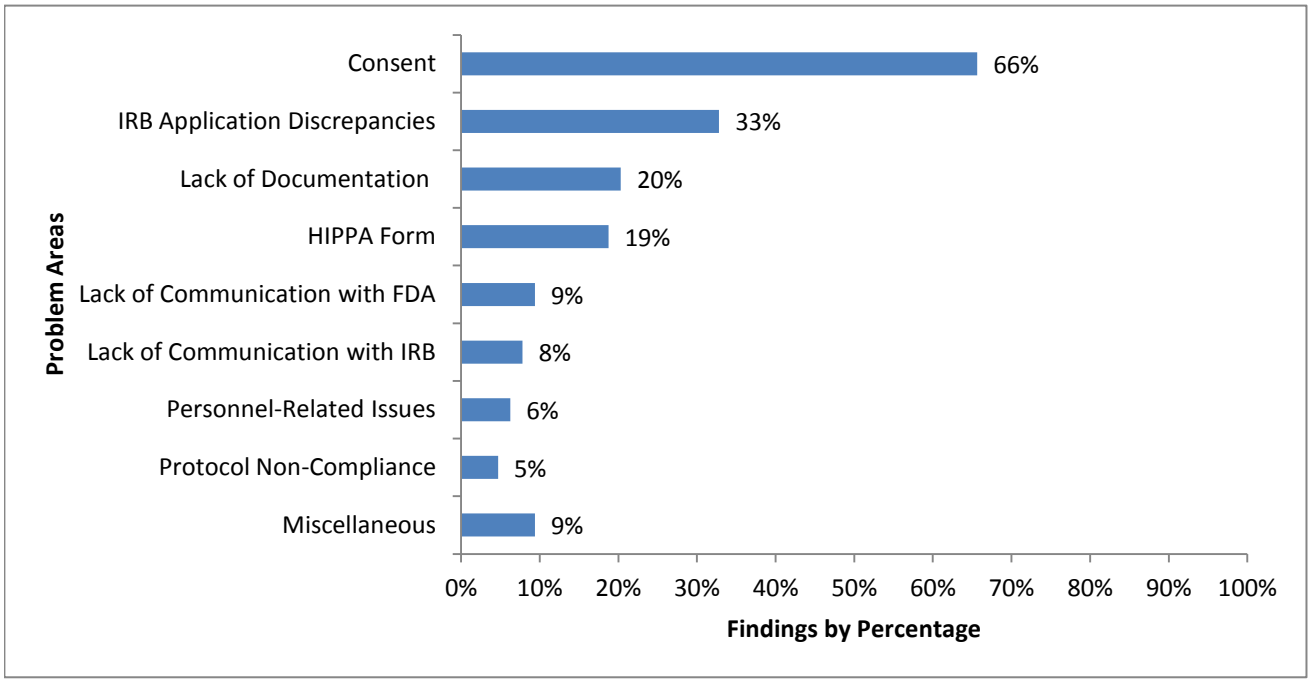
Problem Areas Identified in CQI Assessments



CQI AT-A-GLANCE

First assessment: 5/2008
To Date: 21 Assessments; 2 required Follow-up (21 investigators; 23 visits)
Total Number of Studies Audited: 64
11 UPC investigators
10 HSC investigators

DETAILS OF PROBLEM AREAS

Consent + HIPAA form Issues: *no documentation of consent; use of unapproved consent; missing subject name, signature, or signature date; missing PI signature; use of wrong HIPAA form; HIPAA form not signed by subjects; required fields not completed in HIPAA form*

IRB Application Discrepancies: *discrepancies between IRB application and study procedures; unable to locate approved documents in iStar; study personnel different from those in application; personnel obtaining consent is different from that in application*

Lack of Documentation: *no documentation of subjects meeting inclusion/exclusion criteria; no regulatory binder or substantial documentation missing*

Personnel-Related Issues: *lack of GCP training; lack of personnel; lack of personnel oversight*

Lack of Communication with FDA: *personnel listed on Form 1572 form differs from IRB application; missing information in Form 1572; lack of annual progress report for investigator-initiated studies*

Lack of Communication with IRB: *done in untimely manner; study closure report not submitted; protocol deviations not reported to IRB*

Protocol Non-Compliance: *differences between protocol and study procedures; inclusion/exclusion violations*

Miscellaneous: *potential for subject coercion; funding not distributed to proper channel, investigator unaware of consent requirement for all subjects and study closure responsibilities*